

## REMARKS

Claims 1 to 12 are under examination. Claims 1 and 12 have been amended. Claims 3 and 6 have been cancelled and added into claim 1. These remarks are tendered also in light of an interview with the Examiner on October 13, 2005.

In the office action, there is a note that the Declaration is objected to but there are no comments as to what the objection is. According to our records, the three inventors signed the Declaration, a copy of the Declaration is attached.

1. The Examiner has rejected Claim 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention as noted on Page 2 of the Office Action.

Applicants have amended Claim 12 to overcome this rejection.

2. The Examiner has rejected Claims 1 to 14 under 35 U.S.C. 103(a) as being unpatentable over Farley et al. in combination with Del Giglio for the reasons noted on Page 2 of the Office Action.

A determination as to whether a valid rejection has been made begins with ascertaining that the PTO policy regarding the guidelines laid down by the Supreme Court in Graham v. John Deere, 148 USPQ 459 (Sup. Ct. 1966) has been carried out. The PTO policy is simply that the patent Examiners carry the responsibility of making sure that the standard of patentability enunciated in this decision is applied in each case.

The proper test of obviousness is found in the four Graham inquiries: These inquiries are determining the scope and content of the prior art, ascertaining the differences between the prior art and the claims at issue, resolving the level of ordinary skill in the pertinent art, and considering objective evidence present in the application indicating obviousness or non-obviousness. The issue to be resolved is whether these inquiries have been correctly applied, considered and resolved.

It is further noted that the obviousness rejection should be directed at the claimed invention of the patent application in light of the teachings of the references, not that the

claimed invention could be used on the cited references.

The Examiner states, "Farley et al teach a method of treating venous varicosities by threading a catheter through the venous system and confirming the position thereof with ultrasound, fluoroscopy, or angioscopy."

The use of the present invention in the areas noted is critical to the invention since these tissue areas are delicate tissues and are more likely to suffer damage from applications of the prior devices.

The use of the 980 nm laser has provided surprising results in these areas since prior uses were dedicated to the use of the 980 nm laser for cutting and coagulating tissues in surgery. The 980 nm laser is especially well absorbed in water as it is the second harmonic of the major OH stretching absorption peak at 2.94  $\mu\text{m}$ . The present invention is directed at the goal of collapsing or closing veins in the areas noted in the throat, varices or eye, not cutting the veins and/or merely coagulating them.

Farley et al. discloses a catheter for treating varicose veins with electrodes and an expandable section thereon. The complexity of the Farley et al. device is clearly shown in Figures 2 and 3 and discussed in related text as compared to the optical waveguide of the present invention. The device and method of treatment of Farley et al. is directed at venous insufficiency in the legs, ankles, and feet. See Col. 1, line 28, to Col. 2, line 43. Farley et al. note the treatment of vein valves. Col. 14, line 16. The application of the device of Farley et al. is discussed on Col. 15, lines 52 to 56, "The application of RF energy is terminated after there has been sufficient shrinkage of the vein to alleviate the dilation of the vein near the valve, so as to restore venous function or vulvar competency." Farley notes treatment of hemorrhoids for the purpose of shrinking the vein, Col. 17, line 55, to Col. 18, line 12. As stated, therein, "The electrode applies RF energy at a suitable frequency to minimize coagulation for a sufficient amount time to shrink, stiffen, and fixate the vein, yet maintain venous function ..." Treatment of other areas are noted as penile venous system for the purpose of again shrinking the veins, Col. 18., lines 13 to 33, and esophageal varices, Col. 18, lines 34 to 51. As noted therein, the treatment

shrinks the veins. "The amount of shrinkage of the vein can be limited to the diameter of the catheter itself, ..." Col. 18, lines 27 to 29. Farley notes that other types of energy can be used in this treatment including lasers but fails to teach any details of such an application. Col. 18, lines 59 to 65. Claim 1 includes a step of "molding the hollow anatomical structure to a specific size using external compression." Claim 5 notes the use of a laser, but fails to provide any further details of such treatment.

Farley et al. fail to teach a method of treating varices in the manner of the present invention, in the areas noted, and by means of selective radiation from a 980 nm laser resulting in actual closure, not just shrinkage.

Del Giglio teaches a method and device of applying laser energy to veins, in particular, for the purpose of closure. The laser energy is applied through an optical fiber inserted through a needle. A standard needle is attached to the hand piece and is then inserted through the skin and directly into the desired vascular structure. Col. 5, lines 25 to 30. Del Giglio discloses the treatment of wrinkles in Example 1, skin lifting or contracting in Example 2, superficial capillaries in Example 3, spider veins in Example 4, and varicose veins in Example 5. As to the treatment of other body structures as noted in the present invention, no further details are provided. See Example 6. Further, Del Giglio does not disclose the preferred laser wavelengths in treating various structures.

As noted in Claim 1, the above two references fail to teach the treatment of varices, which as discussed in the office interview, are in particularly more delicate areas of the body and thus require more refined, non-obvious treatment and devices. The beneficial use of laser radiation and laser radiation of 980 nm. is not disclosed in the above two references. The present invention has found that the wavelength of 980 nm to be especially effective in the treatment of varices. See Page 6, lines 8 to 27.

It is therefore asserted that these cited reference(s) clearly does not anticipate the invention for the reasons noted hereinabove. The features claimed in the reference do not function as in the present claims. Further this reference does not anticipate Claims 1 to 19, since its disclosure is not in such full, clear, and exact terms as to enable any person skilled

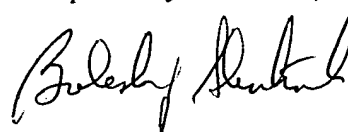
in the art to which the invention relates to practice it.

With these remarks it is believed that the requirements of 35 USC, 37 CFR and the MPEP have been answered and the disclosure and claims are now in condition for examination as one whole invention. Consideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

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